

### **Amendments to the Claims**

This listing of claims will replace all prior versions, and listings of claims in the application.

#### **Listing of Claims:**

1. (Previously presented) An anti-reflux valve prosthesis to be placed in an esophagus, the prosthesis comprising:  
an annular fixation body;  
a plurality of retractable spikes spaced along a circumference of the annular body adjacent one end thereof to secure the prosthesis in the esophagus;  
a one-way valve depending from the annular fixation body, the one way valve configured to allow orthograde passage therethrough and to inhibit retrograde passage of gastric contents; and  
a gas permeable membrane to allow retrograde permeation of a gas therethrough.
2. (Original) The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is configured to be perorally installed.
3. (Original) The anti-reflux valve prosthesis of claim 2 wherein the prosthesis is configured to be perorally removable.
4. (Original) The anti-reflux valve prosthesis of claim 1 wherein the gas permeable membrane is substantially liquid impermeable.
5. (Original) The anti-reflux valve prosthesis of claim 1 wherein the one-way valve is a sleeve valve.
6. (Original) The anti-reflux valve prosthesis of claim 1 wherein the prosthesis is comprised of a biologically inert material.
7. (Original) The anti-reflux valve prosthesis of claim 6 wherein the prosthesis is comprised of a fluorinated polymer.
8. (Cancelled)
9. (Cancelled)
10. (Cancelled)
11. (Cancelled)
12. (Cancelled)

13. (Currently amended) An anti-reflux valve prosthesis for peroral implantation in an esophagus, the prosthesis comprising:  
an annular body;  
a valve depending from the annular body, said valve allowing orthograde passage therethrough and inhibiting retrograde passage of gastric contents; and  
a plurality of spikes spaced along a circumference of the annular body adjacent one end thereof, wherein each of the spikes includes a tip at a free end thereof and a base attached to the annular body and are selectively retractable between a deployed and a retracted alignment with respect to the circumference, and  
a dog formed between a base and a tip of each of the spikes.
14. (Original) The anti-reflux valve prosthesis of claim 13 wherein said valve is a sleeve valve.
15. (Withdrawn) The anti-reflux valve prosthesis of claim 14 wherein said sleeve valve comprises a plurality of magnets, the magnets secured at a distal end thereof to facilitate closure of the sleeve valve.
16. (Original) The anti-reflux valve prosthesis of claim 13 further comprising a gas permeable membrane to allow retrograde permeation of gas therethrough.
17. (Original) The anti-reflux valve prosthesis of claim 16 wherein the gas permeable membrane is substantially liquid impermeable.
18. (Cancelled)
19. (Cancelled)
20. (Currently amended) The anti-reflux valve prosthesis of claim ~~49~~13 wherein a plurality of keepers are positioned on an exterior surface of the annular body for receiving the dogs and locking the spikes in the deployed alignment.
21. (Currently amended) The anti-reflux valve prosthesis of claim ~~48~~13 wherein each of the spikes is outwardly bendable at the base between the retracted alignment and the deployed alignment.
22. (Original) The anti-reflux valve prosthesis of claim 21 wherein said retracted alignment is generally longitudinal.
23. (Original) The anti-reflux valve prosthesis of claim 21 wherein said deployed alignment is generally radially outward.

24. (Original) The anti-reflux valve prosthesis of claim 13 further comprising a tool to perorally insert the prosthesis into the esophagus.
25. (Withdrawn) The anti-reflux valve prosthesis of claim 13 further comprising a tool to perorally remove the prosthesis from the esophagus.
26. (Original) The anti-reflux valve prosthesis of claim 14 wherein the annular body is internally threaded.
27. (Previously presented) The anti-reflux valve prosthesis of claim 13 wherein the valve is implanted to relieve symptoms of a patient with Gastroesophageal reflux disease.
28. (Original) The anti-reflux valve prosthesis of claim 27 wherein the patient does not suffer from esophageal cancer.
29. (Withdrawn) An implantation tool in combination with the anti-reflux valve prosthesis of claim 13, the tool comprising:  
an inner tube and an outer tube, said tubes being generally concentrically aligned;  
a nipple secured to a distal end of the inner tube, the nipple coupled with the annular body of the anti-reflux valve prosthesis; and  
a headpiece secured to a distal end of the outer tube to engage the retractable spikes and outwardly extend them into position by advancing the headpiece into abutment with the nipple.
30. (Withdrawn) The combination of claim 29 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
31. (Withdrawn) The combination of claim 30 further comprising a handle, said handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.
32. (Withdrawn) The combination of claim 31 further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate rotation of the outer tube with respect to the inner tube.
33. (Withdrawn) The combination of claim 29 further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.
34. (Withdrawn) The combination of claim 29 wherein the headpiece includes a plurality of transverse passages formed therein in communication with a transverse bore in a wall of the inner tube and a central longitudinal passage.

35. (Withdrawn) The combination of claim 34 further including a vacuum source in communication with the central longitudinal passage.
36. (Withdrawn) A method for using the tool and valve combination of claim 29 to perorally implant the anti-reflux valve prosthesis in the esophagus, the method comprising the steps of:  
mounting the anti-reflux valve prosthesis onto the headpiece of the tool;  
positioning the anti-reflux valve prosthesis in the esophagus;  
deploying the plurality of radial spikes of the prosthesis;  
pulling a vacuum across a longitudinal passage of the tool; and  
drawing a lumen of the esophagus inwardly to facilitate impaction of the spikes.
37. (Withdrawn) The method of claim 36 wherein the headpiece is configured to be removable and replaced with a crown, the crown configured to assist in the peroral removal of the prosthesis from the esophagus.
38. (Withdrawn) An implantation tool in combination with the anti-reflux prosthesis of claim 13, the tool comprising:  
the anti-reflux valve prosthesis of claim 13;  
means for mounting the anti-reflux valve prosthesis onto a headpiece of the tool;  
means for positioning the anti-reflux valve prosthesis in the esophagus;  
means for deploying the plurality of radial spikes with the tool;  
means for pulling a vacuum across a longitudinal passage of the tool; and  
means for drawing a lumen of the esophagus inwardly for facilitating impaction of the spikes.
39. (Withdrawn) A method for implanting the anti-reflux valve prosthesis of claim 13 in an esophagus, the method comprising the steps of:  
perorally inserting and positioning the anti-reflux valve prosthesis into the esophagus;  
deploying the plurality of spikes, the spikes depending radially from the anti-reflux prosthesis; and  
impaling the esophagus upon the spikes to hold the prosthesis in place.
40. (Withdrawn) The method of claim 39 further comprising using a vacuum to assist in impaling the esophagus upon the spikes.

41. (Withdrawn) An implantation tool in combination with the anti-reflux valve prosthesis of claim 13, the tool comprising:  
means for perorally inserting and positioning the anti-reflux valve prosthesis into the esophagus;  
means for deploying the plurality of spikes, the spikes depending radially from the anti-reflux prosthesis; and  
means for impaling the esophagus upon the spikes to hold the prosthesis in place.
42. (Withdrawn) A method for using the combination tool and valve of claim 29, the method comprising the steps of:  
releasably engaging the nipple of the tool with the annular body of the prosthesis;  
perorally inserting the valve prosthesis into the esophagus near a gastroesophageal junction;  
extending the spikes fully outward into a deployed alignment for engagement with a lumen of the esophagus;  
uncoupling the nipple from the prosthesis; and  
withdrawing the tool from the esophagus.
43. (Withdrawn) The method of claim 42 further comprising actuating a vacuum source to draw a wall of the lumen inwardly and facilitate engagement of the spikes therein.
44. (Withdrawn) An implant tool in combination with the anti-reflux prosthesis of claim 13 in an esophagus, the tool comprising:  
the anti-reflux valve prosthesis of claim 13;  
means for releasably engaging a nipple of the tool with the annular body of the prosthesis;  
means for perorally inserting the valve prosthesis in to the esophagus near a gastroesophageal junction;  
means for extending the spikes fully outward into a deployed alignment for engagement with a lumen of the esophagus;  
means for uncoupling the nipple from the prosthesis; and  
means for withdrawing the tool from the esophagus.

45. (Withdrawn) An extraction tool in combination with the anti-reflux valve prosthesis of claim 13, wherein the prosthesis includes radial spikes extended therefrom, the tool comprising:  
an inner tube and an outer tube, said tubes being generally concentrically aligned;  
a nipple secured to a distal end of the inner tube, the nipple configured to be releasably coupled with the annular body; and  
a crown secured to a distal end of the outer tube, the crown having a plurality of tangentially projecting shoes to receive and retract the extended radial spikes.
46. (Withdrawn) The combination of claim 45 wherein the outer tube is configured to be advanced or retracted as the outer tube is rotated with respect to the inner tube.
47. (Withdrawn) The combination of claim 46 the tool further comprising a handle, the handle being secured adjacent to a proximal end of the inner tube for manipulation thereof.
48. (Withdrawn) The combination of claim 47 the tool further comprising a second handle secured adjacent to a proximal end of the outer tube to facilitate movement of the outer tube with respect to the inner tube.
49. (Withdrawn) The combination of claim 45 the tool further comprising a fiber optic cable disposed within a central longitudinal passage of the inner tube for viewing the esophagus.
50. (Withdrawn) The combination of claim 45 the tool further comprising an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of spikes to facilitate removal of the prosthesis from the esophagus.
51. (Withdrawn) The combination of claim 50 wherein the shield is tapered from a larger diameter at a distal end to a smaller diameter at a proximal end.
52. (Withdrawn) The combination of claim 45 wherein the crown is configured to be removable and replaced with a headpiece, the headpiece configured to assist in reinstalling the prosthesis into the esophagus.
53. (Withdrawn) A method for using the tool and valve combination of claim 45 to extract the valve prosthesis from an esophagus, the method comprising the steps of:

- perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;
- engaging the nipple into the annular body of the prosthesis, wherein the plurality of spikes are extended;
- advancing the crown with respect to the nipple, the crown configured to retract the spikes; and
- removing the tool and engaged prosthesis from the esophagus.
54. (Withdrawn) The method of claim 53 further comprising advancing a shield over the spikes to place the spikes into a retracted position.
55. (Withdrawn) An extraction tool in combination with the anti-reflux prosthesis of claim 13, the tool comprising:
- means for perorally inserting the tool into the esophagus, wherein the tool comprises a nipple and a crown;
- means for engaging the nipple into the annular body of the prosthesis, wherein the plurality of spikes are extended;
- means for advancing the crown with respect to the nipple, the crown configured to retract the spikes; and
- means for removing the tool and engaged prosthesis from the esophagus.
56. (Currently amended) The anti-reflux valve prosthesis of claim 13, wherein the annular body includes a biologically inert polymer, further comprising: a plurality of substantially rigid spikes spaced along a circumference of the annular body adjacent one end thereof extending radially outwardly from the annular body; and each spike comprising a tip at a free end thereof and a base attached to the annular body; wherein each spike is temporarily inwardly bendable for implantation and has memory to return to the radially outwardly extending position.
57. (Withdrawn) An implantation tool in combination with the anti-reflux valve prosthesis of claim 56, wherein the annular body is internally threaded and the spikes are attached to a proximal end of the annular body, comprising:
- an inner tube;
- a nipple secured to a distal end of the inner tube for releasably threadably coupling the annular body;

a handle secured adjacent to a proximal end of the inner tube for manipulation thereof;  
an overtube slideable along and receiving the inner tube;  
a handle secured to a proximal end of the overtube for manipulation thereof;  
a shield attached to a distal end of the overtube longitudinally movable between a first position for receiving the fixation spikes in the inwardly bent configuration during peroral insertion into the esophagus, a second position for releasing the fixation spikes, and a third position for facilitating return of the fixation spikes to the memory position.

58. (Withdrawn) A method for using the tool and valve combination of claim 57 for implanting the anti-reflux valve prosthesis, comprising the steps of:  
threadably engaging the nipple in the annular body;  
bending the spikes inwardly and positioning the shield in the first position over the spikes;  
perorally inserting the valve prosthesis into the esophagus near a gastroesophageal junction;  
while holding the valve prosthesis in place, moving the shield into the second position to release the spikes to return to the memory position;  
optionally moving the shield into the third position to facilitate return of the spikes into the memory position to facilitate engagement of the spikes in a wall of the esophagus;  
rotating the inner tube with respect to the annular body to uncouple the nipple; and  
withdrawing the tool from the esophagus.
59. (Withdrawn) The method of claim 58 further comprising moving the shield into the third position to facilitate return of the spikes into the memory position to facilitate engagement of the spikes in a wall of the esophagus.
60. (Withdrawn) An extraction tool in combination with the anti-reflux valve prosthesis of claim 56 wherein the annular body is internally threaded and the spikes are attached to a proximal end of the annular body, comprising:  
inner and outer concentric tubes;  
a nipple secured to a distal end of the inner tube for threadably coupling the annular body;



a handle secured adjacent to a proximal end of the inner tube for manipulation thereof;  
wherein the inner tube and the outer tube are in threaded interengagement for advancement of the outer tube by rotating the outer tube with respect to the inner tube;

a crown secured to a distal end of the outer tube and having a plurality of tangentially projecting shoes disposed on a distal end of respective longitudinal arms spaced along a circumference of the crown in correspondence with the spikes for bending the fixation spikes inwardly;

an overtube having a shield of enlarged diameter at a distal end thereof, wherein the overtube is slidable over the outer tube to receive the plurality of inwardly bent spikes within the shield to inhibit laceration of the esophagus during movement of the prosthesis.

61. (Withdrawn) A method for using the tool and valve combination of claim 60, comprising the steps of:

perorally inserting the tool into the esophagus and threadably engaging the nipple in the annular body of the prosthesis;

while holding the inner tube in place, rotating the outer tube with respect to the inner tube to advance the crown with respect to the nipple, engage the spikes with the shoes and bend the fixation spikes radially inwardly;

advancing the overtube to position the shield over the inwardly bent spikes;

withdrawing the tool and the prosthesis from the esophagus.

62. (Withdrawn) A implantation tool in combination with the anti-reflux prosthesis of claim 56, the tool comprising:

means for bending the plurality of spikes inwardly and means for positioning a shield in a first position over the spikes;

means for perorally inserting the prosthesis into the esophagus near a gastroesophageal junction;

means for moving the shield into a second position while holding the prosthesis in place to release the spikes into the memory position;

means for rotating an inner tube of the tool with respect to the annular body of the prosthesis to uncouple a nipple of the tool from the prosthesis; and

means for withdrawing the tool from the esophagus.

63. (Withdrawn) An extraction tool in combination with the anti-reflux prosthesis of claim 56, the tool comprising:

means for perorally inserting the tool into the esophagus and threadably engaging a nipple of the tool in the annular body of the prosthesis;

means for rotating an outer tube of the tool with respect to an inner tube of the tool while holding the inner tube in place to advance a crown of the tool with respect to the nipple, to engage a plurality of spikes of the prosthesis with a plurality of shoes of the crown, and to bend the spikes radially inwardly;

means for advancing an overtube of the tool to position a shield of the tool over the inwardly bent spikes; and

means for withdrawing the tool and the prosthesis from the esophagus.